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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,582	10/31/2003	Meir Stern	85189-5300	1887

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,582	STERN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38,40-48,50 and 53-79* is/are pending in the application.

4a) Of the above claim(s) *40-48,50,53-55 and 57-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/2204; 05/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' election with traverse of Group II, claims 22-38, 56, is acknowledged. The traversal is on the ground(s) that independent claims 40 and 50 are now amended to depend from claim 22 and should be rejoined since the only use of the presented printed patch is for administration of an active agent by a transdermal route. However, the instant claims are still distinct inventions, though related as product and process claims. As explained in the restriction requirement, where Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Applicants further submit new claims 57-79, which are supported by initial claims 1-21, 51, and 52, are dependent on claim 22 and should also be examined by the other current claims. This is not found persuasive because as explained in the restriction requirement, the transdermal delivery system comprising an apparatus capable of generating a micro-channel is or can be materially different from the patch product of the elected claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21, 39, 49, 51-52 are canceled. Claims 40-48, 50, 53-55, 57-79 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 22-38, 56 are currently under examination.

Priority: The benefit date is October 31, 2002, for the purpose of prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-25, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Haralambopoulos (US 5958447). Haralambopoulos teaches a transdermal patch comprising a bioactive substance can be formulated as a powder, liquid, or semi-liquid, e.g. gel or emulsion, and applied between the adhesive surface of a tape and its release liner (or its backing layer, for a transfer tape) (col. 3, lines 5-20). In Figures 1-3, Haralambopoulos teaches an active substance (or mixture of substances) in powder form is sprinkled, deposited, or spread uniformly as a thin layer on an exposed adhesive surface of a patch of a prefabricated pressure sensitive adhesive tape, which is comprised of a backing layer and a pressure sensitive adhesive matrix (col. 6 lines 45-50; claims 22-25). Haralambopoulos teaches the incorporation of powdered ascorbic acid into a transdermal patch (col. 8 lines 6-9; lines 22-25). Further alternative techniques of incorporating the powdered bioactive substances into a transdermal patch are disclosed in Figures 4-7, i.e. inter-laminarly (col. 9 lines 32-65; claims 22-25). The stability of the powdered bioactive substance taught by Haralambopoulos is inherent and should therefore anticipate instant claim 37 because it meets the patch of Haralambopoulos anticipates and meets the limitations of claim 22.

Claims 22-26, 28-29, 37, 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Jang (US 5611806). Jang teaches Korean patent publication 92-2264 discloses a patch-type device for transdermally delivering insulin to patients (col. 1 line 48). The insulin delivery patch-type device comprises an insulin solvent reservoir constituting a water-swellable, high molecular, insulin-carrying layer on which insulin is dispersed in a powder form, a needle support adapted to expand as the insulin solvent is discharged from the reservoir and an electrode attached to the ceiling of the reservoir (col. 1 lines 50-60; claims 22-26, 28-39, 37, 56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447). The teachings of Haralambopoulos are outlined above. In column 6, line 47, Haralambopoulos disclose an active substance (or mixture of substances) in powder form can be sprinkled or spread uniformly as a thin layer on an exposed surface adhesive surface of a patch. Additionally, Haralambopoulos teaches ascorbic acid can be combined and formulated with additional carriers, i.e. glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, ethanol, lanolin, and mineral oils (col. 12 line 30).

In view of modern pharmaceutical practice, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a buffering agent or a preservative into a mixture of substances, including a bioactive substance, in powder form into the transdermal patch of Haralambopoulos because Haralambopoulos disclose a bioactive substance and/or a mixture of substances can be successfully incorporated into a transdermal patch (claim 38).

Claims 26, 28-29, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447) in view of Sintov et al. (US 6274166). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach insulin as an active agent.

Sintov et al. teach a transdermal delivery system comprising an active ingredient selected from the group consisting of peptides, proteins, and mixtures thereof. Topical proteins such as insulin can be incorporated into pharmaceutically acceptable carriers such as gels, ointments, solutions, paste, powder, and an adhesive patch (col. 3 lines 53-56). Further, Sintov et al. disclose the therapeutic proteins and its protectors/stabilizers can be applied as a topical formulation such as a cream, ointment, or gel (col. 4 lines 43-45). Sintov et al. disclose a transdermal patch can consist of several layers including the drug layer containing the adhesive polymer, plasticizer, oxidizing agents, penetration enhancers and other excipients (col. 4 lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising insulin

with additional agents such as stabilizers and/or polymers into the transdermal patch of Haralambopoulos because Sintov et al. teach topical proteins such as insulin can be incorporated into pharmaceutically acceptable carriers and stabilizers in the form of a powder in a transdermal delivery system and Haralambopoulos teach powdered bioactive substances can be spread uniformly as a thin layer on an exposed surface adhesive surface of a patch (claims 26, 28-29, 32-33).

Claims 27, 29, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos (US 5958447) in view of Marin (US 6274582). The teachings of Haralambopoulos are outlined above. Haralambopoulos does not teach human growth hormone as an active agent.

Marin teaches human growth hormone (hGH) can be used in combination with a cortisol synthesis inhibitor in a pharmaceutical composition. Marin discloses hGH formulations may be lyophilized in order to obtain a dry powder (col. 5 lines 27-28). Further, compositions which comprise hGH and saccharose are also disclosed (col. 5 lines 30-32). Marin also discloses the hGH compositions can be formulated as transdermal patches (col. 5 lines 40-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising hGH and saccharose into the transdermal patch of Haralambopoulos because Marin teaches hGH formulations may be lyophilized to obtain a dry powder and formulated into a transdermal patch and Haralambopoulos teach powdered bioactive substances can be

spread uniformly as a thin layer on an exposed surface adhesive surface of a patch (claims 27, 29, 32-34).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 29-36, 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 18-19 of copending Application No. 11327016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '016 claims are both drawn to a printed patch comprising a dried pharmaceutical composition comprising a polypeptide. Additionally, both the instant claims and the '016 claims also recite further elements such as stabilizers, i.e. carbohydrates, amino acids, polymers,

and disaccharides that can be added and/or incorporated into the dried pharmaceutical composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 13, 2006

M. Monshi
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER